ATMOS
MedizinTechnik

English

Operating Instructions

ATMOS C 451

Surgical Suction Unit

340.0300.B USA
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CE 0124

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General Standard Terms and Conditions

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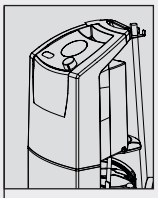
1.0 Introduction

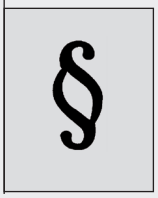
1.1 Notes on operating instructions



These operating instructions contain important notes on how to operate the ATMOS C 451 safely, correctly and effectively. Reading this booklet helps avoid risks, and also to reduce repair costs
and down-time. That increases, amongst other things, the reliability and service-life of the device. These operating instructions serve not only for new operating personnel to be instructed in its use, but also for use as a reference manual. Any reprint - even in extracts - only after written permission from ATMOS.

These operating instructions must always be kept available near the device.

Care and safety inspections in conjunction with professional execution provide for operational safety and readiness for use of your ATMOS C 451 and are therefore a must besides regular cleaning. Repair work and safety inspections may be carried out only by expert personnel authorised by ATMOS. By applying only original spare parts you will have the guarantee that operational safety, readiness for work and the value of your ATMOS C 451 will be preserved.



- The product ATMOS C 451 bears CE marking CE 0124 according to the EC Directive of the council for medical products 93/42/EEC and meets the basic requirements of appedix I of this directive.
- The quality management system applied at ATMOS has been certified according to international standards EN ISO 9001 and EN ISO 13485.
- Prior to start-up please peruse chapter 2.0 „For your safety“, in order to be prepared for any possible dangerous situations.

1.2 Intended use

The Surgical Suction Unit **ATMOS C 451** is a compact suction unit for medical application. It is especially intended for aspiration and collection of secretions, body fluids and tissue.

Its main fields of application are:

– **in the OPD, in the OR:** for sucking off and collecting e.g. drain pockets, abscesses, body and rinsing solutions and during lipectomy;

– **in endoscopy:** e.g. to aspirate secretions or rinsing solutions as well as for operative fixation;

– **in gynaecology:** for suction curettage;

– **In ENT applications:** to aspirate secretions, rinsing solutions, cerumen or to extract foreign matters;

– **in the ward, recovery ward and ICU: :** for the spon-taneous aspiration of body fluids and foreign matters, e.g. from the respiratory tract.

Contraindications for Use:
– Exposed arteries, veins or organs, Untreated osteomyelitis, Necrotic tissue, Malignancies, and Fistulas.
– for smoke evacuation in connection with HF-electrosurgery or laser surgery.

Warning:
– Do not use in non-medical applications;
– Do not use for emergency medical aid.
– Do not use in the presence of combustible or explosive fluids or gases.
– Do not use for drainage in the low vacuum range (e.g. thorax drainage).

Caution: Federal law restricts this device to sale by or on the order of a physician.
- The product ATMOS C 451 bears CE marking CE 0124 according to the EC Directive of the council for medical products 93/42/EEC and meets the basic requirements of appedix I of this directive.
- The quality management system applied at ATMOS has been certified according to international standards EN ISO 9001 and EN ISO 13485.
- Prior to start-up please peruse chapter 2.0 „For your safety“, in order to be prepared for any possible dangerous situations.

1.3 Function

- The ATMOS C 451 is a line-power operated surgical suction unit, centering around a silent diaphragm-type pump which generates a vacuum inside a collection jar. Using a vacuum regulator and the vacuum-gauge, the target vacuum and thus the air-flow rate can be precisely adjusted.

- A system trolley is available for mobile use.

1.4 Explanation of pictures and symbols

Short cuts / symbols contained in this manual

Follow the arrows whilst proceeding, sequence

Please press where dot indicates

Please read, important information

■ General information

● Numeration

→ Subnumeration

Check

Move, plug ... in this direction

Turn, shift ... in this direction

Replace

Engage, check correct fit

Pictures contained in this manual

Warning, especial diligent notice

☞ Important information

Observe operating instructions

Keys on the control panel / symbols at the ATMOS C 451

Potential equalization

~ Alternating current

IPX1 Protection against penetration of damaging humidity (drop water)

Foot switch

Off (feed-in, power connection)

On (feed-in, power connection)

Application part type BF

SN Serial number

REF Order number

Creation date

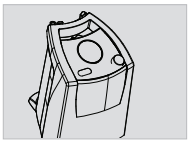
CE 0124 The CE sign shows that this product meets the appropriate requirements of the EC Directives

Protection class II

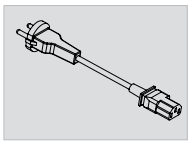
Fuse

1.5 Scope of supply

- Prior to dispatch, this ATMOS device was subjected to an extensive functional test and has been carefully packed. Nevertheless, please compare the contents of the shipment on completeness immediately upon receipt (see delivery note). In addition to the basic device, the scope of delivery comprises the following parts:



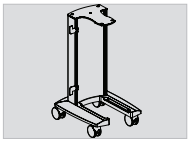
Basic device



Mains cable

Operating instructions

Optional:



System trolley

Trolley

1.6 Transport and storage

- The transport of the device may be effected only in a dispatch carton upholstered and offering sufficient protection.
- Please document and report damages in transit immediately. For complaints or return deliveries, please use the enclosed form **QD 434**.
- The unit must be allowed to stand for up to six hours at room temperature prior to starting up for the first time following transport at temperatures below freezing. The unit may **not** be operated if it has **not** acclimatised as this might damage its diaphragms.
- Ambient conditions:

Transport/Storage:	-22...+122°F; 5...90 % humidity non-condensing at air pressure 700...1060 hPa
Operation:	+50...+95°F; 20...80 % humidity non-condensing at air pressure 700...1060 hPa

2.0 For your safety

For your safety

- The **ATMOS C 451** fully complies with the electromagnetic immunity requirements of standard **IEC 60601-1-2 / EN 60601-1-2** "Electromagnetic compatibility - Medical Electrical Equipment".
- Warranty period for this unit: 2 years. This period is unaffected by any repair or maintenance carried out under the terms of the warranty. Please also pay attention to our enclosed General Standard Terms and Conditions.
- The warranty will be rendered invalid in case of damages caused due to the utilization of accessories or consumables which are not approved by ATMOS for use with this unit.
- ATMOS is not liable for personal injury and damage to property if
  - no original ATMOS parts are being used,
  - the advice for use in these operating instructions is not being observed,
  - assembly, new settings, alterations, extensions and repairs have been carried out by personnel not authorised by ATMOS.
- This operation manual corresponds with the construction of the unit and with the current status of safety-related standards at the time of printing. Proprietary rights are existing for all described circuits, processes, names, software programs and units.
- The design of the **ATMOS C 451** fulfills the requirements of IEC 60601-1/EN 60601-1 and of protection class I. The device must only be connected to a properly installed socket with non-fused earthed wire.
- Before putting the device into operation, visually check unit, power cable and accessories for signs of damage. Damaged cables must be replaced immediately. Check also function of the unit.
- The **ATMOS C 451** may be used in supervised operation by qualified personnel only which has been authorised by ATMOS and which has been trained for operating the appliance (IEC 60601-1/EN 60601-1).
- The **ATMOS C 451** may be operated only in rooms used for medical purposes, but not in areas (zones M and G) subject to **explosion hazards and in oxygen rich environments**. Explosion harzards may result from the use of combustible anaesthetic agents, skin cleansing agents or disinfectants.
- The foot switch is suited for operation in above mentioned areas.
- Liquids must not be allowed to enter the device. Should liquids have penetrated into the device, it must be inspected (danger of an electric shock) and the pump must be decontaminated resp. exchanged (infection risk).
- After transport at cold temperatures (below the freezing point), the unit must acclimatize prior to first use; leave it unoperated at room temperature for a period of up to 6 hours. If the unit is not acclimatized it must not be operated as the membranes of the pump might get damaged.
- Dispose of the packaging material, observing the applicable waste-control regulations.
- Before connecting the device to the power line, check that the voltage and frequency ratings of the power line are similar to those indicated on the device.
- Never connect the unit to defective power sockets or extension cables.
- When disconnecting the device from the power line, first remove the plug from the wall outlet. Then the power cord may be disconnected from the device. Never touch the plug or cord while your hands are wet.
- The ambient conditions specified in section 10.0 must be strictly observed.
- Set up the device so that the operator has a clear, unobstructed view of and easy access to the front panel. The device must be placed on a solid, level surface.
- This product is not re-sterilisable. Repeated reuse of components which are marked with a ⊗ is forbidden. In case of repeated reuse these components lose their function and there is a high infection risk.

Fig. 1.

- Always set the equipment up on a secure, level surface.

Fig. 2. ❶ ❷ ❸

3.1 Operating elements

❶ On/Off switch with pilot lamp
❷ Vacuumgauge
❸ Vacuum controller

3.2 Connection area in unit base

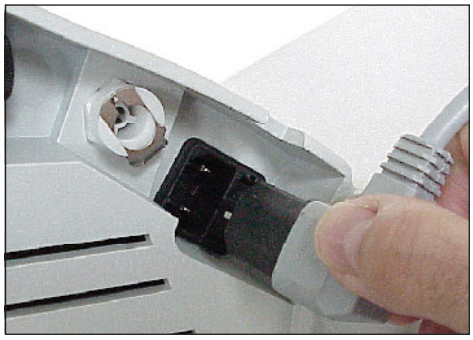


Fig. 4.

Connect mains cable

☞ Use only mains cables with angled inlet connector for non-heating appliances!

- Check that the voltage and frequency ratings of the power line are similar to those indicated on the device.

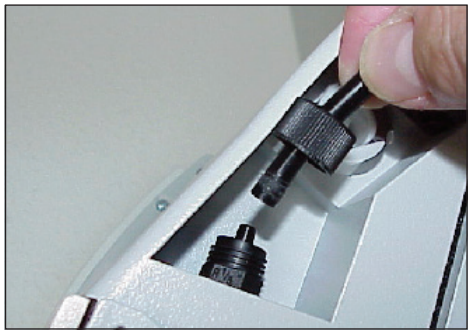


Fig. 5.

Connect footswitch (optional)

- Thread knurled nut onto hose.
- Push hose onto connecting nipple.
- Tighten knurled nut.

Fig.6.

Vacuum connection on base system trolley

- To connect, press coupling firmly into socket until latched into place (serves for vacuum connection of collection jar attached to system trolley).

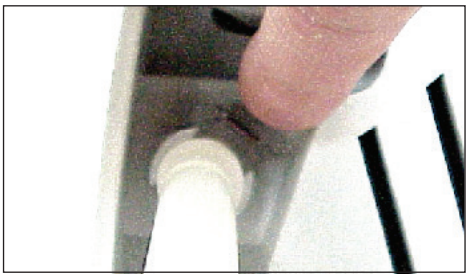


Fig. 7.

- To remove, press the metal interlocking device apart sideways and pull the hose out of the socket.

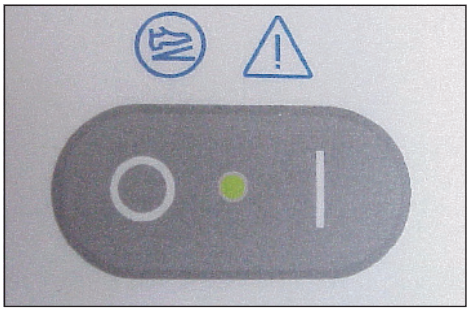


Fig. 8.

4.1 On/off switch

- Press the ”I” symbol to switch the unit on.
- Press the ”0” symbol to switch the unit off.
- The unit is ready for optional footswitch operation in the „0“ position (see options).

Fig. 9.

4.2 Set vacuum

- Close the suction hose and set the desired vacuum by turning the vacuum controller according to the direction of the arrow.

☞ **Do not use force to turn the knob at its limits!**

- Test the system for leaks if the desired vacuum is not reached. (Please also see chapter 8.0 Trouble shooting)

4.3 Suction

- Use appropriate suction tubes, catheters, suction tips or suction instruments, containers and hoses.

☞ Prior to starting suction, containers must be checked for cracks. Damaged containers may not be used.

☞ Keep an eye on the level of liquid in the collection jar during suction.

☞ Use only containers with oversuction protection.

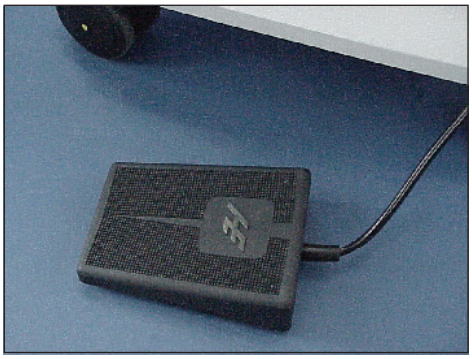


Fig. 10.

5.1 Foot switch (REF 340.0060.0)

- The foot switch works pneumatically and is therefore suitable for use in connection with flammable anaesthetics (class AP).
- Connect the foot switch as shown in section 3.2.
- Set the unit to ”0” off at the main switch (foot switch mode).
- The unit is switched on by pressing the foot switch and switched off by pressing it again.

Fig 11.

5.2 System trolley

- A system trolley, which can be used with a changeover adapter is available for use in the OT.
- Always position the system trolley on a flat, sturdy surface.

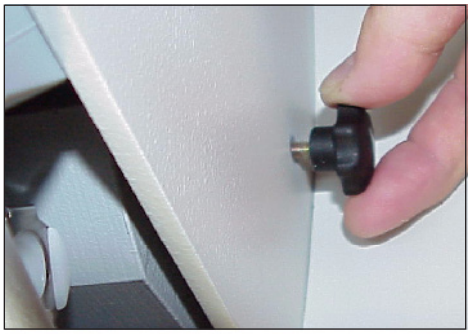


Fig. 12.

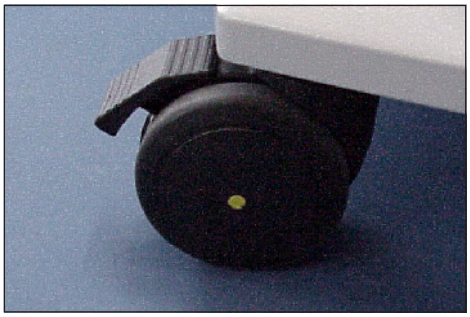


Fig. 13.

Fig. 14.

5.2.1 Securing the unit

☞ It is only possible to ensure safe operation as a mobile suction unit by using the special system trolley available for use with the unit!

- The suction unit is placed on the system trolley so that its feet lock into place in the holes of the unit carrier and it can be firmly attached to the unit carrier from underneath by means of a knurled screw.

☞ It is imperative that the unit is securely attached to the system trolley to ensure safe operation and safe travel!

- Use the lockable castors if necessary.

5.2.2 Travelling with the trolley

- Always push the trolley so that the open fork of the pedestal faces in the direction of travel.
- Push the suction unit using both hands in the handle area.
- Ensure that hoses and cables are secured in place.

☞ Never leave the system trolley on a sloping surface!

Fig. 15.

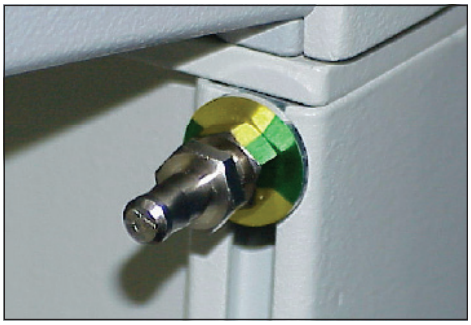


Fig. 16.

Fig. 17.

Fig. 18.

Fig. 19.

5.3 Tray in foot of system trolley (REF 340.0084.0)

- A tray (available as an optional extra) may be inserted in the foot of the trolley.

5.4 Potential equalisation (REF 340.0082.0)

- A potential equalization connector may be installed on the system trolley (in the installation groove) as an optional extra. Installation is performed in accordance with the attached installation instructions.

5.5 Use of suction unit with disposable systems

- The suction unit may also be used as a tabletop unit with disposable systems that can be attached to a standard rail.
- Optionally the suction unit may also be used on the system trolley with disposable systems that can be attached to a standard rail.
- This requires the standard rail set for installation to the trolley in accordance with the attached instructions, and the adapter with standard rail for installation to the securing device of the suction unit as described in the attached installation instructions. This seals the upper vacuum connection and provides the opportunity for attaching additional accessories on the standard rail thus available.
- When using the Receptal canisters the following supports have to be used:

2 x 1,5 l	REF 444.0027.0
1 x 2 l	REF 444.0030.0
2 x 2 l	REF 444.0028.0
1 x 3 l	REF 444.0031.0
2 x 3 l	REF 444.0029.0

5.6 Battery Backup System (Option)

- A Battery Backup (UPS) may be installed on the foot of the system trolley. Can be usefull to brige over blackout / brownout. Installation of the board is performed in accordance with the attached installation instructions.

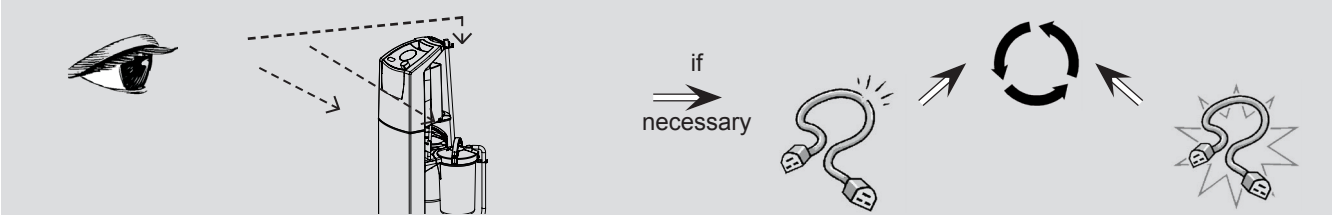
⚠ Make sure to combine the ATMOS C 451 only with Medical Grade UPS in clinical environment.
Follow the instructions of the user manual of the UPS.

6.1 General information on cleaning and disinfection

Prior to cleaning

Medical devices must always offer a maximum in safety and function.
We therefore recommend:

Prior to each application:



☞ The measures described herein regarding cleaning and disinfection do not replace the regulations valid for operating the device!

☞ The information regarding concentration of cleaning liquids and disinfectant solutions stated by the relevant manufacturers must strictly be observed!

6.2 Cleaning and sterilizing the unit surface

☞ Always disconnect the device from the power line, before cleaning and disinfecting the surface.

- Wipe the surface clean with a cloth soaked in a cleaning solution or disinfectant. Liquids must not enter the device. All of the cleaning solutions and disinfectants listed below can be used.

☞ Should liquids have penetrated into the device, it must be inspected (danger of an electric shock) and the pump must be decontaminated resp. exchanged (infection risk).

- Using the cleaning agent Neodisher AN (manufactured by Dr. Weigert, Hamburg) cleaning in an automatic cleaner and disinfecter is also possible.
  Thermal disinfection is carried out at 93° C.

6.3 Recommended disinfectants for instruments

Disinfectant	*Contents*	*(in 100 g)*	*Manufacturer*
GIGASEPT FF neu (Anwendungskonzentrat)	succinic acid dialdehyde dimethoxy tetrahydrofurane corrosion inhibitors non-ionic tensides	11,0 g 3,0 g	Schülke & Mayr, Norderstedt
Sekusept aktiv	sodiumpercarbonate, phosphonates non-ionic tensides		Ecolab, Düsseldorf
neodisher AN	Phosphate non-ionic tensides Enzyme	> 30 g < 5 g	Dr. Weigert, Hamburg

6.0 Cleaning

6.4 Recommended disinfectants for surfaces

Disinfectant	Contents	(in 100 g)	Manufacturer
Mikrobac forte	benzyl - C12 - C18 - alkyldimeththyl - ammoniumchloride	19,9 g	Bode Chemie, Hamburg
	N- (3-Aminopropyl) - N - dodccylpropane- 1,3 - diamine	5,0 g	
Green & Clean SK (Anwendungs-konzentrat)	alkyl-dimethyl-benzyl-ammoniumchloride dialkyl-dimethyl-ammoniumchloride	< 1 g	Metasys, Rum (Österreich)

6.6 Recommended cleaning agents

Disinfectant	Ingredients	(in 100 g)	Manufacturer
neodisher MediClean forte (Application concentrate)	non-ionic tensides NTA (nitrilotriacetic acid) enzymes, preservative agent	< 5 g 5-15 g	Dr. Weigert, Hamburg
neodisher AN	Phosphate non-ionic tensides enzymes	> 30 g < 5 g	Dr. Weigert, Hamburg

7.0 Maintenance

Maintenance

Before putting the device into operation, visually check unit, secretion canister and power cable, accessories, connection cables and hoses for signs of damage. Damaged cables and hoses must be replaced immediately!

However, every 2 years an inspection and a safety-related check according to EN/IEC 62353 have to be performed.

Repairs

The following may require repairs from the manufacturer or an authorized service partner. Prior to sending in the device, please contact your service partner by phone.

- Liquids have penetrated the device
- Sudden occurrence of unusual noises
- Operational and functional disorders which cannot be resolved by means of the hints describes in the chapter “Troubleshooting”.

Measures to be taken prior to sending in the device:

If the device has to be sent in for repair after consultation with the manufacturer or an authorized service partner, we ask you to observe the following:

- Please send in the complete device (see scope of delivery).
- Please remove all disposable parts and consumables.
- Thorough cleaning and disinfection
- Airtight packing
- Please enclose a detailed error description.

Warranty

ATMOS cannot guarantee an error-free function nor can ATMOS be held liable for damage to people or goods if

- non-original ATMOS parts are used,
- the information in these operating instructions are disregarded,
- assembly, new installations, modifications, extensions and repairs are done by people who are not authorised by ATMOS.

7.0 Maintenance

- Visually inspect the device, jar and power cord before each use.
- The unit does not require any further maintenance.

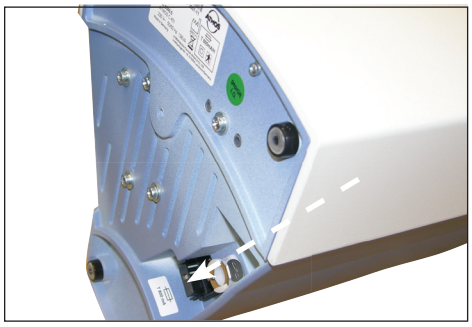


Fig 20.

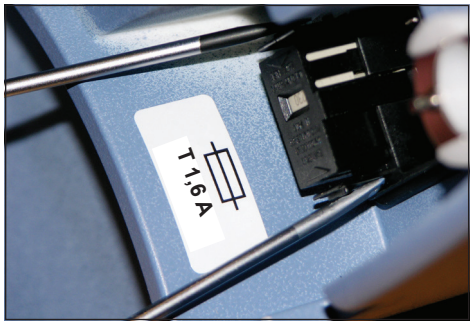


Fig 21.

7.1 Change fuse

- Remove mains cable.
- Press the spring clips of the fuse holder together on both sides with a small screwdriver and pull out the fuse holder.
- Replace the fuse and push the holder back in until both spring clips are locked into place.
- Then reconnect mains cable.

Fuse REF 008.0749.0

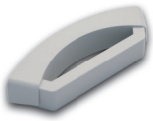
8.0 Trouble shooting

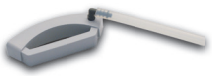
The **ATMOS C 451** was subjected to a thorough quality control before shipment. If there is, nevertheless, some malfunction, you possibly might solve this problem yourselves if you observe the following instructions:

Problem	*Possible cauces*	*Remedy*
● Unit does not start	– Loose power plug	– Check connection to supply socket
	– no power voltage	– Check inbuilding fuse
	– Defective fuse	– Replace fuse
● Insufficient performance or no suction	– Leakages within the hose system or in the collection jar lid	– Check collection jar lid and hose system, replace sealing ring on collection jar lid, if necessary
	– Filter is clogged (vacuumgauge indicates a vacuum)	– Replace filter, check filling level in collection jar; evacuate jar, if necessary
	– Secretion or blood has been sucked in and valve plates of the pump are contaminated	– Unit has to be returned for repair

9.0 Accessories, consumables and spare parts

①

② 

③ 

	REF
Accessories for ATMOS C 451	
Standard rail set for system trolley (instead of DDS-docking system for 2 system jars)	**340.0081.0**
System trolley, basic version for ATMOS C 451	**340.0070.0**
Potential equalization for system trolley	**340.0082.0**
① **Trolley with standard rail**	**320.0070.1**
② **Trolley with standard rail for ATMOS C 451 basic device**	**340.0058.0**
③ **DDS standard rail adapter 25 x 10 mm** with vacuum connection for the use of disposable systems at the unit	**340.0059.0**
Quick connector for ATMOS C 451	**000.0769.0**
Optional foot switch for ATMOS C 451 when used as desk-top unit or with trolley (installation is effected in factory)	**340.0060.0**
Holder for Battery Backup	**on request**
Battery Backup, Medical Grade	**on request**

9.0 Accessories, consumables and spare parts

Description	*REF*
Bellows, silicone rubber	000.0739.0
Fuse 230 V T 0,63 A/H	008.0634.0
Fuse 115 V T 1,25 A/H	008.0720.0
Mains cable angle-angle, 5 m	008.0818.0
Push-in foot for housing	505.0337.0
Fixing screw for system trolley (star handle)	000.0726.0
Clamping ring for fixing screw	000.0727.0
Operating instructions	340.0300.B

10.0 Technical specifications

Air flow rate of pump	45 l/min +3/-5 l/min
Max. vacuum	-91kPa (-910 mbar oder 682,5 mmHg)*@ NN
Vacuum readout	-1...0 bar ± 16 mbar (Klasse 1,6) ø 63 mm
Additional air regulation	mechanical regulating valve
Voltage	230 V~ (+/-10%) 50/60 Hz (REF 340.0300.0)
Current input (max.)	max. 0,75 A bei 230 V~
Operating time	> 12 h continuous operation without interruption within 24 h
Fuse	T 800 mA/H for 230 V~
Heat emission	max. 173 J/s
Noise level	≤ 48 dB (A) @ 1 m (ISO 7779) bei max. Vakuum
Ambient conditions Transport/storage	-22...+122°F 5...90 % humidity, non-condensing air pressure 700...1060 hPa
Operation	+50...+95°F 20...80 % humidity, non-condensing air pressure 700...1060 hPa
Dimensions HxWxD	H 330 x B 240 x T 260 mm H 1010 x B 360 x T 440 mm (with system trolley)
Weight	Ca. 6,7 kg
Regular safety relevant inspections	Every 2 years
Protection class (EN 60601-1)	II
Degree of protection	Typ BF
Protection category	IPX 1
Classification acc. to Annex IXEEC directions 93/42/EEC	IIa (acc. to EC directive 93/42 EEC)
CE marking	CE 0124
Rules applied	EN 60601-1: 2007 EN ISO 10079-1: 2000
UMDNS-Code	10 - 217
GMDN-Code	36777
REF	340.0300.0 230 V

* 1 bar = 750,06 mm Hg =1000 hPa / depending on ambient air pressure

Technical data issued on: 04.07.2011

11.0 Checking / Reprocessing / Disposal

11.1 Checking ATMOS suction devices

The ATMOS suction devices are maintenance-free in the case they are used according to the operating instructions. However, every 2 years an inspection and a safety-related check according to EN/IEC 62353 have to be performed.

Regular, thoroughly cleaning respectively the operation in line with the operating instructions are assumed.

A regular check of the condensate-controller on the rear side is necessary. Pull out the plastic plug and check the colour at the end of the hose. In case of discolouration/deposits a maintenance measure must be performed by a certified ATMOS service partner!

11.2 Reprocessing

In case secretion was sucked into the device it may not be operated. It must be sent to an ATMOS certified service partner.

Handling of the suction device determines to a large extent its reliability and safety. The hygiene measures described in the previous chapters are necessary measures for the protection of patients and users, and to maintain functional reliability.

11.3 Disposal

- The ATMOS C 451 is not comprised of any hazardous materials.
- The materials of the housing can be recycled completely.
- Prior to disposal, device and accessories must be decontaminated.
- The materials are to be separated carefully.
- Pay attention to country-specific regulations for disposal (e. g. waste incineration).

Disposal within the EC

The suction device described above is a high-quality medical product with a long service life. After its life cycle it must be disposed of professional. According to the EC directives (WEEE and RoHS) the device may not be disposed of in domestic waste. Please observe existing national laws and rules for disposal of old devices.

Disposal within the Federal Republic of Germany

In the Federal Republic of Germany the law for electrical devices (ElektroG) rules the disposal of electrical devices. Since this type of product is mainly used at home for secretion suction in the respiratory tract (after laryngectomy), it must be assumed that those suction devices could be contaminated. Therefore, this type of device is excluded from the law for electrical devices. In order to guarantee a proper disposal of your old device, please either pass on your old device to your specialised dealer or send it directly to ATMOS MedizinTechnik for a professional disposal.

Prior to disposal respectively before transport the device surface must be disinfected.

12.0 Notes on EMC

- Medical electrical equipment is subject to special precautions with regard to EMC and must be installed acc. to following EMC notes.
- Portable and mobile HF communication facilities can influence medical electrical equipment.
- The use of other accessories, other converters and cables than stated may lead to an increased emission or a reduced interference immunity of the equipment or system.

12.1 Guidelines and Manufacturer´s Declaration - Emissions

The ATMOS C 451 is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS C 451 should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The ATMOS C 451 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The ATMOS C 451 is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	match	

The device may not be used directly next to other devices or piled up with other devices.
If operation next to or piled with other devices is necessary, please watch the device to check its intended operation in this arrangement.

12.2 Guidelines and Manufacturer´s Declaration - Immunity

The ATMOS C 451 is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS C 451 should ensure that it is used in such an environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete, or ceramis tile. If floors are synthetic, the relative humidity should be at least 30%.
EFT IEC 61000-4-4	± 2 kV Mains ± 1 kV I/Os	± 2 kV Mains	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV Differential ± 2 kV Common	± 1 kV Differential ± 2 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency 50/60 Hz Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
Voltage Dips / Dropout IEC 61000-4-11	< 5 % U_T (> 95 % Dip of the U_T) for 0.5 Cycle 40 % U_T (60% Dip of the U_T) for 5 Cycles 70% U_T (30 % Dip of the U_T) for 25 Cycles < 5 % U_T (>95 % Dip of the U_T) for 5 s	< 5 % U_T (> 95 % Einbruch der U_T) für 0,5 Periode 40 % U_T (60% Einbruch der U_T) für 5 Perioden 70% U_T (30 % Einbruch der U_T) für 25 Perioden < 5 % U_T (>95 % Einbruch der U_T) für 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ATMOS C 451 demands continued function even in case of interruptions of the energy supply, it is recommended to supply the ATMOS C 451 from an uninterruptible current supply or a battery.
NOTE U_T is the mains alternating current prior to application of the test levels.			

12.3 Guidelines and Manufacturer´s Declaration - Immunity

The ATMOS C 451 is intended for use in the electromagnetic environment specified below. The customer or user of the ATMOS C 451 should ensure that it is used in such an environment.

Immunity Test	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile communications equipment should be separated from the ATMOS C 451 incl. the cables by no less than the distances calculated/listed below. **Recommended distances:** d = [3,5 / 10] √**P** d = [3,5 / 10] √**P** von 80 MHz bis 800 MHz d = [7,0 / 10] √**P** von 800 MHz bis 2500 MHz where „P“ is the max. power in watts (W) and D is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic site (*a*) survey, should be less than the compliance level (*b*). Interference may occur in the vicinity of equipment containing following symbol.
Conducted RF IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	[V_1] V	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E_1] V/m	

NOTE 1	With 80 MHz and 800 MHz the higher frequency range applies.
NOTE 2	These guidelines don´t like to be applicable in any case. The propagation of electromangetic sizes is influenced by absorptions and reflections of buildings, objects and people.
a	The field strength of stationary transmitters, such as base stations of cellular phones and mobile terrain radio equipment, amateur radio transmitters, cbm broadcast and TV stations cannot be predestined exactly. To determine the electromagnetic environment in regard to stationary transmitters, a study of the location is to be considered. If the measured field strength at the location where the ATMOS C 451 is used exceeds the above compliance level, the ATMOS C 451 is to be observed to verify the intended use. If abnormal performance characteristics are noted, additional measures might be necessary, e. g. a changed arrangement or another location for the device.
b	Within the frequency range of 150 kHz to 80 MHz the field strength is to be below 3 V/m.

12.4 Recommended separations between portable and mobile RF Communications equipment and the ATMOS C 451

The ATMOS C 451 is intended for use in electromagnetic environment in which ratiated disturbances are controlled. The customer or user of the ATMOS C 451 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications equipment and the ATMOS C 451 as recommended below, according to the maximum output power of the communications equipment.

	Separation distance, depending on transmit-frequency m		
Nominal output of the transmitter W	**150 kHz bis 80 MHz** **d =** [3,5 / 3] √**P**	**80 MHz bis 800 MHz** **d =** [3,5 / 3] √**P**	**800 MHz bis 2,5 GHz** **d =** [7,0 / 3] √**P**
0,01	0,1	0,1	0,2
0,1	0,4	0,4	0,7
1	1,2	1,2	2,3
10	3,7	3,7	7,4
100	11,7	11,7	23,3

For transmitters for which the maximum nominal output isn´t indicated in the above table, the recommended separation distance *d* in meters (m) can be determined using the equation belonging to the respective column whereas *P* is the maximum nominal output of the transmitter in watts (W) acc. to manufacturer´s specification.

NOTE 1 With 80 MHz and 800 MHz the higher frequency range applies.

NOTE 2 These guidelines are not applicable in any case. The propagation of electromagnetic sizes is influenced by absorptions and reflections of buildings, objects and people.

Declaration of Conformity

ATMOS MedizinTechnik

EG - KONFORMITÄTSERKLÄRUNG
EC - DECLARATION OF CONFORMITY
DECLARATION DE CONFORMITE CE

Wir / We / Nous

ATMOS MedizinTechnik GmbH & Co. KG
Ludwig-Kegel-Straße 16
79853 Lenzkirch/Germany
Tel. +49 7653 689-0

erklären in alleiniger Verantwortung, dass das Medizinprodukt /
declare under our sole responsibility that the medical device /
déclarons sous notre pleine et entière responsabilité que le produit médical

Klassifizierung / Classification / Classification : II a

Name / name / Nom:

ATMOS C 451 ..... REF 340.0300.0

Varianten / models / Variante:

ATMOS C 451 fahrbar 2x3 l REF 340.0334.0
ATMOS C 451 fahrbar 2x5 l REF 340.0333.0

ATMOS C 451 Praxispaket 1,5 l REF 340.0339.0
ATMOS C 451 Praxispaket 3 l REF 340.0338.0
ATMOS C 451
mit Vakuumextraktionspaket REF 340.0355.0

ATMOS C 451 tragbar ..... REF 340.0357.0
mit Normschiene
ATMOS C 451 fahrbar ..... REF 340.0358.0
mit Normschiene

allen anwendbaren Anforderungen der Richtlinie 93/42/EWG entspricht. /
meets all applicable requirements of the Directive 93/42/EEC /
répond à toutes les exigences applicables de la directive 93/42/CEE

Name, Adresse und Kennnummer der Benannten Stelle:
Name, address and identification number of Notified Body:
Nom, Adresse et Numéro d'identification de l'organisme notifié :

CE 0124

DEKRA Certification GmbH, Handwerkstraße 15, D-70565 Stuttgart

Konformitätsbewertungsverfahren:
Conformity assessment procedure:
Procédé d'évaluation de conformité :

Richtlinie 93/42/EWG Anhang II des Rates über Medizinprodukte vom 14. Juni 1993, zuletzt geändert am 5. September 2007 / Directive 93/42/EEC Annex II on medical products, passed by the commission on 14th June 1993, last amended on 5th September 2007 / Directive 93/42/CEE, Annexe II du Conseil sur les produits médicaux, passée en commission le 14 juin 1993, dernière modification le 5 septembre 2007.

Gültig bis auf weitere Änderungen am Produkt bis 29. März 2015.
Valid till further changes on the product until March 29th 2015.
Valide jusqu'à modification du produit, jusqu'au 29 mars 2015.

Lenzkirch, den 04.06.2013
Place and date of issue

Frank Greiser
Geschäftsführer /
Managing Director / Directeur

i.V. Steffi Focke
Sicherheitsbeauftragter / Safety
Inspector / Chargée de la Sécurité

Qd 148-10_CE0124_IIa

Terms and conditions

Applicable to any buyer of ATMOS products

1. General

These Terms and Conditions apply to buyer's purchase of ATMOS products. Buyer's terms and conditions which are contrary to or deviate from ATMOS's Terms and Conditions are not part of any contract between ATMOS and buyer unless ATMOS explicitly accepts them in writing, even if ATMOS has knowledge of the buyer's contrary terms and conditions. ATMOS's Terms and Conditions also apply to all future business with buyer.

2. Quotation; Order Confirmation; Confidentiality

If these terms and conditions are submitted as part of a proposal from ATMOS, then ATMOS reserves the right to modify its proposal including without limitation the price until the final terms are stated in an order confirmation. In addition, ATMOS reserves the right to make design or manufacturing changes at any time without prior notice and without incurring an obligation to modify or change products manufactured or delivered prior to such changes. Each order is considered accepted by ATMOS only following ATMOS's written order confirmation.

All price quotes from ATMOS, and all plans, illustrations, calculations and other documents included with a quote, are confidential and are not to be disclosed by buyer to any other party without first receiving written authorization from ATMOS.

3. Orders

Every order requires an exact description of all of the product's details. ATMOS assumes no liability for errors and damage caused by inaccurate or incomplete ordering details. All orders must be in writing via E-mail, US-mail or fax. Verbal orders are not accepted or binding.

4. Prices; Delivery and Packaging Costs

Unless otherwise stated in the order confirmation, prices are net prices in US Dollar, excluding tax, insurance, packing and shipping costs. The price for this order is not applicable to any other order.

Any and all present or future government charges, levies, or taxes on the products shall be added to the price and paid by buyer unless buyer furnishes ATMOS with an exemption certificate acceptable to the taxing authorities.

Standard shipments are typically UPS Ground. Express service is available at an additional cost.

Packaging is charged to buyer separately at cost.

5. Payment Conditions

ATMOS accepts COD, bank check, money order or most major credit cards (Visa/Mastercard). An account with special payment conditions can be established for qualified buyers.

Once an account is opened all payments are due net 30 days unless otherwise stated in the order confirmation. Any delay in payment of more than 2 weeks will be charged at an annual interest rate of 18% (1.5% per month). No shipments will be made to any delinquent accounts.

6. Delivery Periods and Terms; Risk of Loss

Shipments of products are usually made within 2 weeks of an order unless noted otherwise in an ATMOS order confirmation or other ATMOS document. Buyer will receive a faxed notice with a shipment date for products that are not in stock.

ATMOS is not liable for a delay beyond the promised delivery date or for damages resulting from delivery.

Unless otherwise stated in the order confirmation, delivery is ex factory. The risk of damage or loss to the products is on the buyer as soon as the products leave the factory. Delivery will be insured by ATMOS at buyer's expense unless explicitly otherwise agreed.

No insurance is arranged by ATMOS for products picked up by buyer at ATMOS's factory or place of business.

Buyer is responsible for disposing of the packaging at its own cost.

7. Installation

For products which require specific installation or assembly skills, ATMOS reserves the right to perform such installation and assembly at buyer's delivery location or to deliver the products to an authorized installer and have the authorized installer install and assemble the products at buyer's delivery location. In either case, ATMOS reserves the right to charge the buyer for the additional costs.

8. Manufacturer's warranty

ATMOS warrants that new products sold to buyer will be free from defects in workmanship and material for 24 months after manufacture when properly maintained by buyer and used as intended by ATMOS. ATMOS also warrants that accessories and spare parts will be free from defects in workmanship and material for 12 months from the date of purchase. Any claim under this warranty must be made during the foregoing time periods or is conclusively waived.

This warranty is not assignable and applies only to buyer. In addition, this warranty does not apply in the case of mishandling, incorrect installation or assembly by buyer or an unauthorized third party, incorrect or insufficient maintenance, unacceptable operating conditions (such as unacceptable humidity, ventilation, temperature, power supply, or vibrations), normal wear and tear, changes of any kind to the product without first being authorized by ATMOS, repairs to the products or the use of accessories or replacement parts without first being authorized by ATMOS, incorrect operation of the product, improper use, inappropriate or negligent handling and care, especially with respect to dirt, lime, suction of fluids, inappropriate cleaning and sterilization, accidents, or acts of God.

No warranty is given with respect to disposable items.

In the event a product fails in normal use because of defects in workmanship or materials, buyer's exclusive remedy will be the repair or, at ATMOS's sole option, the replacement of the defective product. At the sole choice of ATMOS, ATMOS or an authorized repairer may provide repair services either on the buyer's premises or elsewhere. To exercise this remedy, buyer must provide proof of purchase from ATMOS and the product must still have the original serial number. In addition, if required by ATMOS, the buyer agrees to send the product freight prepaid in its original or similar packaging, offering the same protection as the original packaging, to the shipping address provided by ATMOS.

THE FOREGOING WARRANTY IS EXCLUSIVE AND IS GIVEN IN LIEU OF ALL OTHER WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

9. LIMITATION OF LIABILITY

The remedies of buyer set forth herein are exclusive and the total liability of ATMOS with respect to this order and buyer's subsequent ownership and use of the product, whether based on breach of contract, breach of warranty, negligence, indemnification, strict liability or otherwise, and even if ATMOS has been advised of the possibility of damages, shall not exceed the purchase price of the product or component upon which liability is based. In no event shall ATMOS be liable for consequential, incidental or special damages, including buyer's loss of profits or liabilities of buyer to any third persons.

10. Return policy

Any ATMOS product which buyer is not satisfied with (except customized products e.g. ENT workstations, patient chairs) can be returned within 14 days for a full refund less shipping charges. It must be received in the original packaging with the proper documentation and in its original condition. Please contact ATMOS for a "Return Material Authorization" (RMA) number before returning any products.

All items returned for service or calibration must contain paperwork describing the reason for return, contact name, phone and fax number. ATMOS will provide buyer with a quotation prior to any non-warranty service.

Costs for shipping, calibrations and service are non-refundable.

11. Exclusive Jurisdiction; Waiver of Trial by Jury

Any action by buyer against ATMOS must be brought in the court of appropriate jurisdiction in Lehigh County, Pennsylvania or the United States District Court for the Eastern District of Pennsylvania. Buyer consents to the exclusive jurisdiction of these courts and waives all claims of improper venue and jurisdiction. BUYER WAIVES TRIAL BY JURY WITH RESPECT TO ALL DEMANDS, CLAIMS, AND COUNTERCLAIMS RESULTING FROM THE PURCHASE, RENTAL, MAINTENANCE, OR USE OF THE PRODUCTS PURCHASED HEREUNDER.

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